UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/307,633	05/07/1999	KENNETH J. NIEHOFF	L-F/104H	5115

26875 7590 06/28/2006

WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
AHMED, AAMER S	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/307,633
Filing Date: May 07, 1999
Appellant(s): NIEHOFF, KENNETH J.

Thomas W. Humphrey
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 17 2006 appealing from the Office action mailed November 15 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,383,858	REILLY et al.	3-1987
4,636,198	STADE	1-1987
4,652,260	FENTON	3-1987
2,966,175	HYDE	12-1960

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 22, 24, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (US 5,383,858 A), in view of Applicant's disclosure on Page 3, lines 7-33, or alternatively in view of Stade (US 4,636, 198 A).

Reilly et al. discloses a front-loading medical injector, which may be used with a standard empty syringe (to be filled at the time of use) or a pre-filled syringe (22), comprising a body (32) having a closed forward end (34/36) with a nozzle (86), an open rearward end, and including structure mountable in an injector (27), a plunger (38) located within the body, the empty syringe and the pre-filled syringe both having a capacity, and physical indicia (70/70b/70s) interacting with the injector on one of the syringes indicating information related to the capacity of the syringe, i.e. the dimensions of the syringe, the content, (defined as the amount of specified material contained, see Merriam Webster's Collegiate Dictionary (tenth edition) © 1997, content on page 250), of the syringe in the case of a pre-filled syringe, manufacturing information, recommended contrast media flow rates/pressures, and loading/injection sequences, see Column 6, lines 45-51.

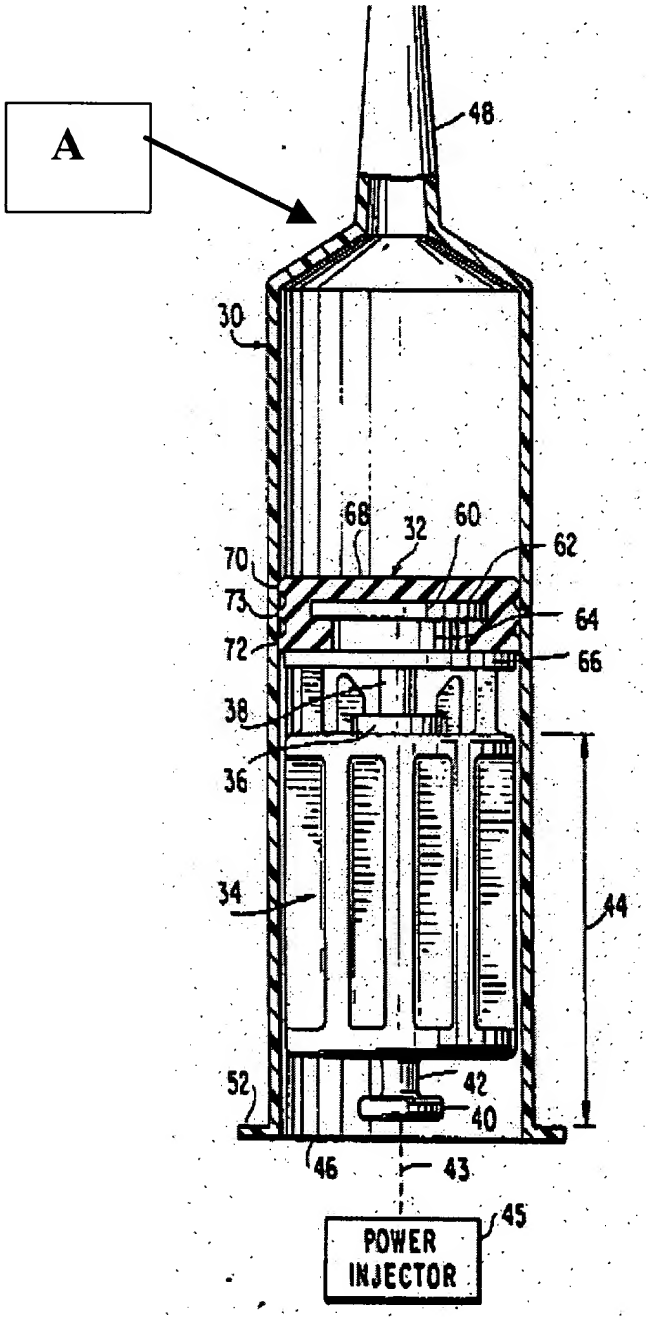
Reilly et al. fails to disclose the pre-filled syringe being pre-filled to a capacity with an amount of fluid different than a first capacity of an empty syringe.

Applicant's admission of prior art on Page 3, lines 21-25 of Applicant's originally filed specification, discloses pre-filled syringes are sold in a number of capacities, e.g. ranging from 50 to 125 milliliters, allowing the operator preparing for an injection to select a syringe containing only as much media as is needed for the injection', and on Page 4, lines 2-8, discloses in Figure IB a prior art pre-filled syringe having an extender (16).

It would have been obvious to one having ordinary skill in the art to have modified Reilly et al.'s front-loading medical injector with a pre-filled, disposable syringe including an extender, so as to allow the syringe to be filled with only as much media as will be needed, thereby

preventing infection due to contamination and allowing for cost-effective dosing to minimize waste and in order to accurately measure and record the amount of reagent delivered.

Alternatively, Stade discloses a power syringe with volume reducing adapters comprising a power injector (45), a syringe body (30) having a closed forward end (A, see labeled figure)



having a nozzle (48), an open rearward end (46), a plunger (32) located within the body. The power injector may be used with pre-filled syringes having standard dimensions, standard pistons, and different content volumes by way of volume reducing adapters having various fluid displacing lengths.

It would have been obvious to one having ordinary skill in the art to have utilized the front-loading medical injector of Reilly et al with pre-filled syringes having volume reducing adapters therein as taught by Stade, so as to provide a syringe for containing a reduced volume of contrast media which is suitable for being utilized in existing power injectors, and to avoid costs associated with the manufacture, inventory and supply of different syringe sizes.

Furthermore, Hyde U.S. Patent 2,966,175 provides support for providing volume and capacity indicia on syringes as described by Reilly et al (Hyde col. 4 line 31 and col. 5 line 36).

Claims 22, 24, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stade (US 4,636, 198 A) in view of Reilly et al. (US 5,383,858 A).

Stade discloses a power syringe with volume reducing adapter comprising a power injector (45), a syringe body (30) having a closed forward end (A, see labeled figure above) with a nozzle (48), an open rearward end (46), a plunger (32) located within the body. The power injector may be used with pre-filled syringes having standard dimensions, standard pistons, and different content volumes by way of volume reducing adapters having various fluid displacing lengths.

Stade fails to disclose a physical indicia interacting with the injector on the syringe indicating information related to the capacity of the syringe.

Reilly et al. discloses a front-loading medical injector, which may be used with a standard syringe to be filled at the time of use or a pre-filled syringe (22), comprising a body (32) having a closed forward end (34/36) with a nozzle (86), an open rearward end, and including structure mountable in a common injector (27), a plunger (38) located within the body, the empty syringe and the pre-filled syringe both having a capacity, and physical indicia (70/70b/70s) interacting with said common injector on one of the syringes indicating information related to the capacity of the syringe, i.e. the dimensions of the syringe, the content (defined as the amount of specified material contained, see Merriam Webster's Collegiate Dictionary (tenth edition) © 1997, [4]content on page 250) of the syringe in the case of a pre-filled syringe, manufacturing content on page information, recommended contrast media flow rates/pressures, and loading/injection sequences see Column 6, lines 45-51.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Stade's syringe with a physical indicia capable of interacting with the injector to indicate information related to the capacity of the syringe, so as to enable the injector to read the physical indicia on the syringe and to cause the generation of signals therefrom to regulate the injector controller in order to adjust the function (i.e. flow rates and pressures) of the injector accordingly.

Furthermore, Hyde U.S. Patent 2,966,175 provides support for providing volume and capacity indicia on syringes as described by Reilly et al (Hyde col. 4 line 31 and col. 5 line 36).

Claims 22, 24, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenton, Jr. et al. (US 4,652,260 A) in view of Stade (US 4,636, 198 A).

Fenton, Jr. et al. discloses an infusion device/powered syringe, for use with different size syringes, the syringes respectively comprising a body (20) having a closed forward end (138) see Figure 12, with a nozzle (146) and an open rearward end (no reference numeral, interpreted as the end adjacent flange (158) which slidably receives plunger rod (34), the body of each syringe having a diameter and including structure mountable in a common injector (10), a plunger (no reference numeral, interpreted as the piston (not shown) at the distal end of plunger rod (34) located within the body, the syringes having different capacities, and physical indicia (126) interacting with the common injector on one syringe indicating information related to the capacity of said syringe, see Column 7 line 57 to Column 8 line 3 – line 65.

Fenton, Jr. et al. fails to disclose the different sized/capacity syringes having a common diameter.

Stade discloses a power syringe with volume reducing adapters comprising a power injector (45), a syringe body (30) having a closed forward end (A, see labeled figure above) having a nozzle (48), an open rearward end (46), a plunger (32) located within the body. The power injector may be used with pre-filled syringes having standard dimensions, standard pistons, and different content volumes by way of volume reducing adapters having various fluid displacing lengths.

It would have been obvious to one having ordinary skill in the art to have modified Fenton, Jr. et al. with syringes having different capacities via volume reducing adapters, while

maintaining the same diameter so as to avoid costs associated with the manufacture, inventory and supply of different syringe sizes.

Allowable Subject Matter

Claims 23, 25, 27, 29 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(10) Response to Argument

Applicant's arguments filed April 17, 2006 have been fully considered but they are not persuasive.

Regarding the independent claims 22, 24, 26, 28 and 30, appellant maintains that the combination of the Reilly et al reference '858 in view of the Stade reference '198 or alternatively in view of Stade '198 fails to render the claims obvious.

Appellant argues that Reilly et al '858 does not teach physical indicia interacting with the injector, specifically that "content" as disclosed in the Reilly et al '858 reference does not refer to the capacity of the syringe.

However as discussed above, the dictionary definition of "content" is relied upon in interpreting the meaning of the term content, defined as the amount of specified material contained, see Merriam Webster's Collegiate Dictionary (tenth edition) © 1997, [4]content on page 250.

Furthermore Reilly et al '858 discloses that the indicia (76) indicates the presence of liquid, and thereby indicates a volume of liquid present in the syringe.

Additionally, Reilly et al '858 clearly discloses that the indicia could include dimension of the syringe (col. 6 line 45), from which content of the syringe is determined.

Moreover, applicant asserts that the Fenton reference '260 when combined with Stade '198 fails to disclose physical indicia.

As discussed above, Fenton '260 discloses that "detection of the position of the connector 126 in the infusion device 10 will determine whether small or large syringes may be emptied at higher speeds than larger syringes, with the position of the connector being used to control the speed of the drive motor assembly . . . The infusion device 10 is arranged to provide different rates of plunger travel depending on size of the syringe 20 in the syringe compartment."

Therefore Fenton '260 uses the position of the connector, as well as the size of the syringe to determine the rate of the plunger travel.

In addition Hyde '175 discloses that the volume of a syringe is indicated via communication with physical indicia on a syringe "As the driven spurt gear 42 revolves, the counter switch opens and closes . . . to register calibrated counts representative of the volume of reagent delivered" Column 5 line 9.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Aamer S. Ahmed

Examiner
Art Unit 3763

Conferees:

Nicholas Lucchesi

Anh-tuan Nguyen